



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,247	09/25/2001	David A. Ferrick	A-66038-1/RMS/DLR	9693
959	7590	02/09/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 02/09/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/963,247

Applicant(s)

FERRICK ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17,19-22 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,17,19-22 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 01222002
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The restriction requirement has been withdrawn based on Applicant's argument. Claims 16-17, 19-22, 30-34 are pending and under consideration.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17, 19-22, 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to A method of screening for a bioactive agent that modulates IgE production, said method comprising: a) contacting a candidate bioactive agent and a cell expressing IgE, wherein said cell comprises an IgE fusion protein comprising: i) an E heavy chain; and ii) a fluorescent protein; and b) determining the amount of IgE produced in said cell; wherein a change in the amount of IgE as compared to the amount produced in the absence of said candidate agent indicates that said agent modulates IgE production. There are several problems with the claims as written such that the skilled artisan would not be able to practice the claimed method. First, the claims require the presence of an IgE fusion protein in the cell, yet the method is directed to identifying an agent that modulates IgE production. Since the IgE is already present it is not clear how the skilled artisan could then measure the effect on IgE production upon the addition

of the agent. Secondly, it is not clear to one of skill in the art whether the cell expresses IgE endogenously or whether the only IgE present is that which is in the fusion protein. As such, the skilled artisan is not able to practice the method because the method does not set forth whether to measure fluorescence of the fusion protein, or the amount of the endogenously produced IgE. If the method is to measure endogenously produced IgE, the role of the fusion protein in the method is not apparent. If the method is to measure the effect of a bioactive agent on the IL-4 inducible promoter, the claims do not require the presence of a nucleic acid comprising this promoter that encodes a fusion protein comprising the epsilon heavy chain and a fluorescent protein. Perhaps the method is meant to be directed to the measurement of the effect of a compound on the half-life of the fusion protein, but there is no step whereby the protein is measured over time. Since the claims are directed to methods of screening for bioactive agents which modulate IgE production, and since the steps set forth do not enable the skilled artisan to practice such a method, the claims as written are not enabled.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17, 19-22, 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is vague and indefinite in that it is not clear whether the cell expresses IgE endogenously, or whether the IgE fusion protein itself meets the limitation that the cell expresses IgE. Furthermore, as set forth *supra*, it is not clear how the method would detect an effect on

Art Unit: 1646

IgE production, since the production of IgE is not necessarily dependent on the presence of the fusion protein, and further, the fusion protein is not, e.g. encoded by a nucleic acid comprising an inducible promoter. Furthermore, the method does not set forth that the IgE produced is determined by measuring the fluorescent protein, only by measuring IgE, thus the presence of the fusion protein would seem to have no role in the method as written. If the method is meant to be directed to the measurement of the effect of a compound on the half-life of the fusion protein, there is no step whereby the protein is measured over time. Claims 17, 19-22, 30-34 are vague and indefinite insofar as they depend on claim 16.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,219,752 (Takazawa et al.).

U.S. Patent No. 5,733,731 (Schatz et al.)

U.S. Patent No. 5,804,387 (Cormack et al.)

U.S. Patent No. 5,834,266 (Crabtree et al.)

U.S. Patent No. 5,958,707 (de Vries et al.)

Mikita T et al. Requirements for interleukin-4-induced gene expression and functional characterization of Stat6. *Mol Cell Biol.* 1996 Oct;16(10):5811-20

Persons DA et al. Retroviral-mediated transfer of the green fluorescent protein gene into murine hematopoietic cells facilitates scoring and selection of transduced progenitors in vitro and identification of genetically modified cells in vivo.

Blood. 1997 Sep 1; 90(5): 1777-86.

Art Unit: 1646

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
January 21, 2004